AUG 1 5 2001

K011544

APPENDIX E

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1.0 Date Prepared:

May 15, 2001

2.0 Contact:

John J. Shea, President
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90 Poteskeet Trail
Kitty Hawk, NC 27949
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3.0 Name of Device:

Proprietary Name:	HADgel™
Common Name:	Epistaxis Balloon
Classification Name:	Balloon, Epistaxis (Nasal) (Ear, Nose and Throat 77EMX)

4.0 Device Description:

HADgel™ is a sterile, transparent and viscoelastic gel composed of a cross-linked hyaluronate hydrogel, a derivative of sodium hyaluronate. Sodium hyaluronate is a naturally occurring constituent of extracellular matrix. HADgel™ is prefilled into a single-use disposable syringe. Each syringe contains four (4) grams of HADgel™. This syringe has an adaptor end to facilitate its connection to a standard malleable irrigator for injecting HADgel™ into the nasal/sinus cavity. Due to its physical properties, HADgel™ can conform to mucosal surfaces and sinus cavities. HADgel™ may leave the site of placement by natural elimination, however, residence time is intended to be at least seven (7) days after which removal is recommended.

5.0 Intended Use:

HADgel™ is intended for use as a packing in the nasal/sinus cavities as an aid in maintaining these passages open following surgery during the healing process and to help control minimal bleeding following surgery.

6.0 Devices to Which Substantial Equivalence is Claimed:

Both MeroGel™ Nasal Dressing and Sinus Stent and Hylasine™, hylan B gel are marketed for use in nasal/sinus cavities as space-occupying materials and to help control minimal bleeding after surgery. Both of these predicate approved medical devices are made from materials which have satisfactory biocompatibility, are sterile and are for single use only.

HADgel™ is substantially equivalent to these two devices in that it has similar intended use and indications. HADgel™ also has demonstrated satisfactory biocompatibility, is for single use only and is sterile.

HADgel™ differs from MeroGel™ Nasal Dressing and Sinus Stent in that HADgel™ is a transparent and viscoelastic gel made from a different hyaluronic acid derivative whereas MeroGel™, an ester of hyaluronic acid, has the appearance of spun cotton which after implantation becomes a gelatinous mass and requires manual removal of this sponge-like mass using forceps. HADgel™ since it is in gel form can be more easily removed using suction.

Although HADgel™ and Hylasine™ are similar in appearance, HADgel™ is a cross-linked hyaluronate hydrogel and Hylasine™, hylan B gel is cross-linked polymers of hyaluronan, also a hyaluronic acid derivative with a different cross-linking structure.

In conclusion, HADgel™ has the same intended use as the marketed predicate devices and differs only in the material and/or form of the product. These devices all are intended to be used as nasal/sinus packings and to help control minimal bleeding following surgery. Therefore, HADgel™ is substantially equivalent to these predicate devices in composition and intended use. Based on the data in this submission, HADgel™ presents no safety concerns.

7.0 Summary of Safety and Performance Studies

HADgel™ has been evaluated through the following animal safety and performance studies, summaries of which are included in the Summary of HADgel™ Testing (Biocompatibility) Section of this 510(K) application.

A. ISO EVALUATION TESTS

1. Cytotoxicity

SR00085 – Cytotoxicity Test of HADgel™ using L929 Cells

2. Irritation/Intracutaneous Reactivity

SR00086 – Intracutaneous Injection Test of HADgel™ in Rabbits

SR00087 – Eye Irritation Test of HADgel™ in Rabbits

3. Sensitization

SR00088 – Skin Sensitization Study of HADgel™ in Guinea Pigs

B. In-house Studies

1. Systemic Toxicity (acute)

55-011 - Single dose oral toxicity study of HADgel™ in rats

2. Implantation

0107 - Intracutaneous injection test of HADgel™ in guinea pigs

C. Performance Tests

1. Preservation of nasal space effect with HADgel™ using the nasal mucosa peeling rabbit model
2. Hemorrhage controlling effect of HADgel™ on nasal mucosa peeling model in rabbit
3. Hemorrhage controlling effect of HADgel™ in the abdominal-aorta-puncture hemorrhage rat model

COMPARISON TABLE

Device	HADgel™	Hylasine™	MeroGel™ Nasal Dressing and Sinus Stent
Sponsor	SEIKAGAKU CORPORATION	Biomatrix, Inc.	Xomed Inc.
510(k) Number	K011544	K993362	K982731
Class	Class I	Class I	Class I
Common Name	Epistaxis Balloon	Epistaxis Balloon	Epistaxis Balloon
OTC/Rx	Prescription use	Prescription use	Prescription use
Indication for Use	HADgel™ is intended for use as a packing in the nasal/sinus cavities as an aid in maintaining these passages open following surgery during the healing process and to help control minimal bleeding following surgery.	The intended use of Hylasine™ is for use in nasal/sinus cavity as a space-occupying gel stent, to separate mucosal surface and to help control minimal bleeding following surgery or nasal trauma.	MeroGel™ Nasal Dressing and Sinus Stent is intended for use in the nasal/sinus cavities as a space-occupying dressing and/or stent, to separate mucosal surfaces and to help control minimal bleeding following surgery.
Device Material	cross-linked hyaluronate hydrogel (Hyaluronic acid derivative)	cross-linked polymers of hyaluronan (Hyaluronic acid derivative)	an ester of hyaluronic acid (Hyaluronic acid derivative)
Bio-compatibility testing performed	A. Materials were tested in accordance with ISO 10993 under GLP conditions Body contact: Mucosal membrane Contact Conditions: Category B - Cytotoxicity testing - Intracutaneous reactivity testing - Eye Irritation testing - Sensitization testing	A. TRIPARTITE NONCLINICAL STUDIES (GLP) 1. Short Term Biological Tests 1.1 Irritation Tests 1.2 Sensitization and Immunogenicity 1.3. Cytotoxicity 1.4. Acute Systemic toxicity 1.5. Hemocompatibility and Hemolysis 1.6. Pyrogenicity 1.7. Implantation 1.8. Mutagenicity 2. Long Term Biological Tests 2.1. Subchronic Toxicity 2.2. Chronic Toxicity and Carcinogenicity	not included in 510(k) summary

Device	HADgel™	Hylasine™	MeroGel™ Nasal Dressing and Sinus Stent
	B. Additional Studies - Systemic Toxicity (Acute) - Implantation	2.3. Reproduction Studies 3. Pharmacokinetics B. BASIC EXPLORATORY STUDIES(SUPPORTIVE STUDIES) 1. Short Term Biological Tests 1.1 Acute Irritation 1.2 Sensitization/Immunization studies 1.3 Cytotoxicity 1.4 Acute Systemic toxicity 1.5 Hemocompatibility and Hemolysis 1.6 Pyrogenicity 1.7 Implantation 2. Long Term Biological Tests 3. Pharmacokinetics	
Performance Testing	Animal Tests -Preservation of Nasal Space in Rabbits -Hemorrhage Controlling Effect in Rabbits -Hemorrhage Controlling Effect in Rats	PRECLINICAL PERFORMANCE STUDIES - The use of Hylasine™, Hylan B Gel, in Sinonasal Surgery: A Pilot Study(Rabbits) - The Influence of HylanGel on the Healing of Full Thickness Excision Dermal Wounds in Guinea Pigs CLINICAL SAFETY AND EFFICACY STUDY	not included in 510(k) summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 5 2001

Seikagaku Corporation
c/o Mr. John J. Shea
President
John J. Shea & Associates
90 Poteskeet Trail
Kitty Hawk, NC 27949

Re: 510(K) Number: K011544
Trade/Device Name: HADgel™ Pack
Regulation Number: 21 CFR 874.4780
Regulatory Class: Class I
Product Code: LYA
Dated: May 18, 2001
Received: May 18, 2001

Dear Mr. Shea:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR-Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

II. INDICATIONS FOR USE STATEMENT

Applicant: **SEIKAGAKU CORPORATION**

510(K) Number (if known): K011544

Device Name: **HADgel™**

Indications for USE: HADgel™ is intended for use as a packing in the nasal/sinus cavities as an aid in maintaining these passages open following surgery during the healing process and to help control minimal bleeding following surgery.

(Please do not write below this line-continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE L or Over-the-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011544